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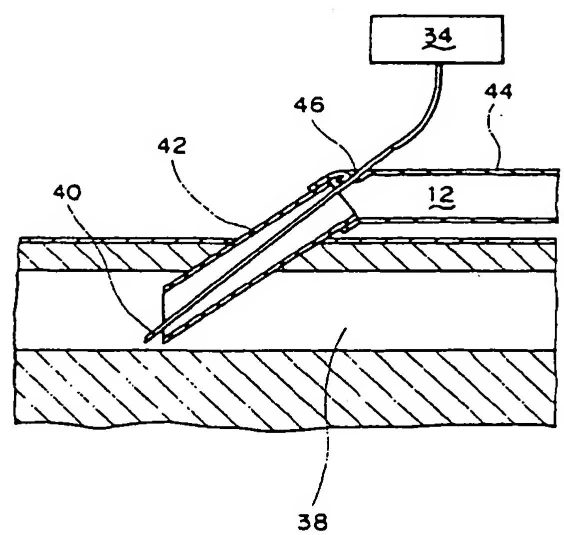
(54) **Blood clarification apparatus.**

(57) A blood clarification device wherein a means for measuring blood pressure (34) comprises (a) a needle-detector (40) which is much thinner than the puncture needle (42) and capable of being smoothly inserted into a blood vessel (38) from outside through an inner aperture of the puncture needle, (b) an insertion aperture (46), for allowing fluid-tight insertion of the needle-detector (40), positioned on a wall of the blood supply passage in the vicinity of the puncture needle (42), and (c) a pressure transducer (34) for detecting the blood pressure inside the blood vessel (38) transmitted thereto via the needle-detector (40). In a blood clarification apparatus of the present invention, blood pressure inside a blood vessel is transmitted to a pressure transducer (34) via a needle-detector (40) during dialysis/filtration operation and blood pressure of a patient is detected continuously and automatically by the pressure transducer (34). A counterplan such as control of water-removing-rate or supplying-supplementary-fluid-rate based on the detected blood pressure is automatically carried out, so that safety of dialysis/filtration operation can be effectively improved.

FIG. 2



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The present invention relates to a blood clarification apparatus. Particularly, the present invention relates to a blood clarification apparatus wherein occurrence of hypotension attack can be effectively prevented during dialysis/filtration operation, and safety and operation characteristics can be effectively improved.

Recently, a medical treatment by blood clarification, using so-called artificial organ, is generally employed and its distinguished effect is recognized. In the treatment, blood once taken out from a living body is circulated through a housing enclosing a semipermeable membrane, the blood is subjected to a predetermined clarifying action by dialyzing or filtering action with the semipermeable membrane, the amount of the blood is controlled by removal of water, and thereafter the blood is brought back into the living body. Thus, renal function and liver function are artificially achieved. For example, a medical treatment by blood dialysis or filtration with the use of so-called artificial kidney, which is applied to a renal insufficiency patient, is a typical one.

Hereupon, in carrying out blood clarification with an artificial kidney, it is necessary to take out blood from a spot of a living body where enough amount of blood can be obtained. Since enough amount of blood is difficult to be obtained from a vein existing in a vicinty of body surface, an operation named shunt is generally performed. The shunt is an operation wherein, for example at a region such as an arm, one of arteries existing in deep area of a body is connected with a vein existing in a vicinity of body surface to bypass them. By this method, an amount of blood running through a vein can be increased. Then, a thick needle (an puncture needle) generally of 15 to 17 gage is used to puncture the fistula, namely the arteried vein, and blood is taken out at a rate of about 250 mℓ /min by using a blood pump to lead the blood to a clarification device. In this device, clarification and removal of water in the blood are carried out.

Due to the above-mentioned treatment, there sometimes happens a phenomenon wherein blood pressure is abnormally lowered during the dialyzing, in a certain patient undergoing medical treatment by the blood dialyzing (the word "dialyzing" used hereinafter includes filtration). This sharp lowering of blood pressure causes symptoms of vomiting and cramp, and loss of awareness. In an extreme case the lowering of blood pressure make a patient be confronted by death. This is so-called a dialysis hypotension. It is recognized that 10 to 20 % of all patients received shock two or three times in one medical treatment by blood dialyzing.

In order to prevent the occurrence of dialysis hypotension symptoms during the dialysis operation, it is necessary to measure blood pressure of the patient continuously and to consider counterplans such as control of water-removing-rate and/or supply of supplementary fluid into blood based on the change of blood pressure.

However, since conventional dialysis apparatus does not have a suitable means for automatically measuring blood pressure, it is necessary that a nurse or the like measures blood pressure at a predetermined time interval by usual ausculation, and manually controls water-removing-rate or supplies supplementary fluid. The operation takes a great deal of trouble for the patients and operators. Moreover, since the dialysis hypotension occurs at intervals of one or two minutes, it is very difficult to find immediately the occurrence of the shock as well as to predict the occurrence of the shock based on the above-mentioned measurement of blood pressure at a predetermined time interval. For this reason, the counterplan for the shock is apt to be late.

Hitherto, in order to measure blood pressure in a blood vessel, it has been carried out that there has been produced a needle having two apertures parallel to each other wherein one of the apertures is utilized for taking out blood from a blood vessel and the other is utilized for transmitting blood pressure inside the blood vessel to a pressure transducer. However, the needle having two apertures is expensive because of its complicated producing steps. Further, since its outer diameter becomes much thicker than that of conventional puncture needles, the blood stanching is very difficult after taking out the needle. For these reasons, the needle having two apertures has not been used practically.

The present invention was made to solve the above-mentioned drawbacks, and it is an object of the present invention to prevent the dialysis hypotension by continuously and automotially measuring blood pressure during dialysis/filtration operation and by enabling the control of water-removing-rate or supply of supplementary fluid based on measurement of blood pressure.

In accordance with the present invention, there is provided a blood clarification apparatus wherein (1) blood taken out from a blood vessel by an puncture needle is introduced to a blood clarification device via a blood supply passage and is clarified by dialyzing and/or filtering action, and water contained in the blood is removed; and (2) blood pressure inside the blood vessel is continuously measured by a means for measuring blood pressure, and water-removing-rate and/or supplementary-fluid-supplying-rateinto a body is controlled based on the measured blood pressure characterized in that

the means for measuring blood pressure comprises a needle-detector, which is much thinner than the puncture needle and capable of being smoothly inserted into a blood vessel from outside through an inner aperture of the puncture needle,
an insertion aperture, for allowing fluid-tight insertion of the needle-detector, positioned on a wall of the blood supply passage in the vicinity of the puncture needle, and
a pressure transducer for detecting the blood pressure inside the blood vessel transmitted to the pressure transducer via the needle-detector.

In a blood clarification apparatus of the present invention, blood pressure inside a blood vessel is transmitted to a pressure transducer via a needle-detector which is to be positioned, during dialysis/filtration operation, in a body via an inner aperture of an puncture needle. Blood pressure of a patient is detected continuously and automatically by the pressure transducer, and a counterplan such as control of water-removing-rate or supply of supplementary fluid based on the detected blood pressure is taken so that safety of dialysis/filtration operation can be effectively improved.

Further, in the apparatus of the present invention, a needle-detector for detecting blood pressure is inserted through an insertion aperture for needle detector made on a wall of a blood supply passage (normally defined by synthetic resin tube) at downstream of an puncture needle for taking out blood. The needle-detector is further brought into a blood vessel through an inner aperture of the puncture needle, so that it is not necessary to directly stick a needle-detector additionally into a blood vessel through a skin. For this reason, the apparatus of the present invention does not give pain and discomfort to patients.

It is a characteristic of the apparatus of the present invention that air is not introduced into blood or blood does not leak out from the insertion position of a needle-detector, since the insertion aperture has good sealing characteristic and the outer diameter of the needle-detector is thin enough. Further, it is a great characteristic of the apparatus of the present invention that the pointed head of the needle-detector is always kept deep enough inside the blood vessel, since the insertion aperture for needle-detector is arranged at a suitable position on a wall of a blood supply passage (synthetic resin tube) positioned at a downstream of the puncture needle.

Further, the apparatus of the present invention can be produced economically because the above-mentioned means for measuring blood pressure employs a constitution wherein a needle-detector of a simple structure is introduced into a blood vessel through an inner aperture of a conventional puncture needle, and blood pressure transmitted via the inner aperture of the puncture needle is measured. Since the needle-detector having sufficiently thin outer diameter relative to the inner diameter of the puncture needle is employed, there is no danger that the existence of the needle-detector causes large resistance against blood current running through the puncture needle.

Fig. 1 is an schematic explanatory view of an embodiment of a blood clarification apparatus of the present invention;

Fig. 2 is an explanatory view showing a means for detecting blood pressure in the apparatus of Fig. 1;

Fig. 3 shows two graphs wherein the upper graph indicates blood pressure detected, with a needle-detector placed inside an puncture needle, continuously during actual dialysis operation using the blood clarification apparatus shown in Figs. 1 and 2, and the lower graph indicates blood pressure detected with a normal needle punctured into an artery; and

Fig. 4 shows two graphs indicating average value of blood pressure shown in Fig. 3 wherein the upper graph is concerned with blood pressure detected with the needle-detector placed inside the puncture needle, and the lower graph is concerned with blood pressure detected with the normal needle punctured into the artery.

Next, an embodiment of a blood clarification apparatus of the present invention is explained below in detail with reference to drawings.

Fig. 1 is a schematic view of a blood clarification apparatus of the present invention. In Fig. 1, numeral 10 represents a dialysis device (dialyzer) comprising a housing in which film-like, tube-like or hollow-fiber-like semipermeable membrane is enclosed. The dialysis device 10 is connected with a blood supply passage 12 for introducing blood taken out from a patient body via an puncture needle 42 (refer to Fig. 2). A predetermined amount of blood is introduced to the dialysis device 10 by a blood pump 14 positioned at a path of the blood supply passage 12. The blood clarified by the dialysis device 10 is returned to the patient's body through a blood carry passage 16. The blood supply passage 12 and the blood carry passage 16 are equipped with an air chamber 18 respectively so that air is prevented from entering the patient's body.

A dialyzate supply passage 20 and a dialyzate discharge passage 22 are connected with the dialysis device 10. The passage 20 serves to introduce dialyzate to the device 10. The passage 22 serves to discharge dialyzate brought in contact with blood through the semipermeable membrane in the dialysis device 10, or to discharge undesired or harmful substance taken out from blood by dialyzing and/or filtering action of the semipermea-

ble membrane. At a respective path of the dialyzate supply passage 20 and the dialyzate discharge passage 22, a known control device 24 for dialyzate supply and water removal is arranged. The device 24 controls dialyzate flow rate and dialyzate pressure. By this control device 24, pressure difference between blood side and dialyzate side which are partitioned by the semipermeable membrane in the dialysis device 10 is controlled, and the removal of water from the inside of body is carried out depending on the pressure difference.

A fluid carry passage 28 communicating with a tank 26 for supplementary fluid is connected with the path of the blood carry passage 16. In the tank 26 electrolyte (supplementary fluid) such as physiological salt solution is contained. By a fluid carry pump 30 arranged at a path of the passage 28, the electrolyte is supplemented or supplied to concentrated blood after filtration. The blood whose composition of blood component is controlled by the above-mentioned operation, is returned to the patient's body through the blood carry passage 16.

In the present embodiment, as shown in Fig. 1, the operation of the control device 24 for dialyzate supply and water removal which controls the amount of water removal by the dialysis device 10 and the operation of the fluid carry pump 30 which controls the amount of supply of supplementary fluid are controlled by a water-removal/supplementary-fluid-supply control device 32. The control device 32 is connected with a pressure transducer 34 which measures blood pressure. The blood pressure value of the patient input from the pressure transducer 34 is compared with a reference value predetermined by a setting device 36. Based on the compared value, the device 32 controls the operation of the device 24 and the pump 30.

As shown in Fig. 2, a needle-detector 40, the pointed head of which is introduced into a blood vessel 38 lying for example in an arm of a patient, is connected with the pressure transducer 34. Thus, blood pressure inside the blood vessel 38 is transmitted to the pressure transducer 34 via the needle-detector 40. The inner aperture of the needle-detector 40 is filled with physiological salt solution so that blood does not enter the needle-detector 40. When the needle-detector 40 is sticked into the blood vessel 38 in an inverse direction to that of blood current, the blood pressure inside the blood vessel 38 is transmitted to the physiological salt solution inside the needle-detector 40 and is further transmitted to the pressure transducer 34. By this way, the blood pressure inside the blood vessel 38 can be continuously detected by the pressure transducer 34.

The needle-detector 40 is not directly sticked into the arm of the patient, but is introduced deep enough to reach inside of the blood vessel 38 through an inner aperture of an puncture needle 42 which is sticked into the blood vessel 38 for taking out blood from the body. That is, in the present embodiment, the needle-detector 40 is inserted into a blood path through an insertion aperture 46 and is led into the blood vessel 38 through the inner aperture of the puncture needle 42. The insertion aperture 46 for the needle-detector 40 is formed on a wall of a tube 44 made of synthetic resin in the vicinity of the puncture needle 42. The tube 44 is connected with the puncture needle 42 and serves as a blood supply passage 12. Concreatly speaking, the insertion aperture 46 is formed on the wall at a position apart from a connected area of the puncture needle 42 and the tube 44 by 5 to 10 mm. The insertion aperture 46 is formed with a member having a good sealing characteristic such as rubber valve.

When the needle-detector 40 is placed as stated above, the patient is not pierced with an additional needle for measuring blood pressure. Further, once the needle-detector 40 is applied to the patient, attachment or detachment of the needle-detector 40 is not carried out till the dialysis is finished, thus, the installation of the needle-detector 40 is not a burden for the patient. Since blood pressure is detected continuously and automatially by the pressure transducer 34 during dialyzing operation by merely attaching and detaching the needle-detector 40 respectively one time, the burden at monitoring fluctuation of blood pressure can be much lowered for a blood pressure measurer.

The pressure inside the inner aperture of the tube 44 and the puncture needle 42, both of which serve as the blood supply passage 12, becomes low not more than the atmospheric pressure by the operation of the blood pump 14. For example, when blood is taken out at a rate of 200 mℓ /min, the inside pressure becomes about -40 mmHg. So if the pointed head of the needle-detector 40 exists in the puncture needle 42, one might think a possibility that blood pressure transmitted through the needle-detector 40 becomes much lower than the arterial pressure under the influence of such negative pressure. However, if the pointed head of the needle-detector 40 is so placed as to sufficiently project from the pointed head of the puncture needle 42 so that the pointed head of the needle-detector 40 reaches a deep position in the blood vessel 38, blood pressure in the blood vessel 38 can be measured exactly almost without the influence of the negative pressure.

Considering the above-mentioned condition, in the present embodiment, the insertion aperture 46 is formed on the wall of the synthetic resin tube 44, which is connected with the puncture needle 42, at a suitable distance from the connected area with

the puncture needle 42. Therefore, the needle-detector 40 can be much easily inserted from the aperture 46, and the pointed head of the needle-detector 40 can be kept at a suitable position in the blood vessel 38. Moreover, by employing an insertion aperture having a good sealing characteristic as the insertion aperture 46, it is effectively prevented that air enters blood or blood leaks out from the insertion aperture 46. Though the puncture needle 42 and the detector-needle 40 are generally applied to a shunted blood vessel, the other artery or vein can be suitably selected so long as sufficient amount of blood to carry out the desired dialysis/filtration operation can be obtained.

One might consider that the insertion of the needle-detector 40 through the puncture needle 42 increases a resistance against blood current in the puncture needle 42. However, when a very thin needle having an outer diameter of about 25 gage is employed as the needle-detector 40, the existence of the needle-detector 40 does not increase the resistance against blood current in the needle 42 and in the tube 44, because as the puncture needle 42 one having an outer diameter of 15 to 17 gage is usually employed to obtain enough blood and as the tube 44 one having an inner diameter of about 6 mm is employed.

In the above-mentioned blood clarification apparatus, the value of blood pressure detected by the pressure transducer 34 through the needle-detector 40 is input to the water-removal/supplementary-fluid-supply control device 32 and the value is compared with the reference value previously set by the setting device 36. Thus, conditions of the patient during the dialysis/filtration operation can be monitored automatically and continuously, and treatments suited to the conditions are carried out automatically and quickly.

A lower limit of blood pressure (for example 70 % of initial value of blood pressure) and allowable maximum decreasing rate of blood pressure (for example 20 mmHg/min) are previously set by for example the setting device 36, and value of blood pressure input from the pressure transducer 34 is compared with the set value in the device 32. When the input value is out of the tolerance, suitalbe treatment is carried out, that is, an operation signal is transmitted to the dialyzate-supply/water-removal control device 24 and to the fluid carry pump 30 so that the operation of the device 24 is controlled to make the amount of the water removal substantially zero, and a predetermined amount of supplemetary fluid is supplied into the blood vessel at a constant rate (for example an amount of about 100 mℓ and a rate of about 200 mℓ /min) by the pump 30.

A dialysis operation was carried out with the blood clarification apparatus shown in Figs. 1 and 2 with a fistula of an arm of a patient being installed with the puncture needle 42 and the needle-detector 40. The value of blood pressure continuously detected during the operation is partly shown in Figs. 3 and 4. In Fig. 3, variation between maximum and minimum blood pressure is shown and in Fig. 4 the average value thereof calculated mathematically is shown. In both Figs. 3 and 4, the upper graph indicates blood pressure measured by the needle-detector 40 placed within the puncture needle 42. The dialysis operation was controlled depending on this variation of blood pressure. The lower graph indicates blood pressure (arterial pressure) measured by an usual needle for measuring blood pressure sticked into an artery of another arm of the patient for comparison. The upper and lower graphs are recognized to have the same correlation, whereby it is found that a blood pressure corresponding to an arterial pressure is exactly detected by the needle-detector 40 placed within the puncture needle 42.

In this dialysis operation, the amount of blood current was set at 200 mℓ /min, and water removal was stopped when blood pressure detected was lowered to 70 % (point A in Fig. 3) of an initial value (the value of the blood pressure at the beginning of the dialysis). When it was further lowered to 60 % (point B in Figs.), 100 mℓ of supplementary fluid was supplied at a rate of 200 mℓ /min, and when it rose to 70 % (point C in Figs.) again the water removal was started again. Thereby, the dialysis operation could be continued with effectively avoiding the dialysis hypotension.

Though embodiment of the blood clarification apparatus of the present invention is explained in detail above, it should be noted that it is merely an embodiment and the present invention should not be limited to that embodiment. A dialysis device is employed as a blood clarification device in the above embodiment, however it is needless to say that the present invention can be advantageously applied to a filtration device with which clarification of and water removal from blood is carried out by merely filtering action of semipermeable membrane without using dialyzate, and further to a dialysis/filtration device with which blood is clarified by dialyzing action and filtering action.

In the above embodiment, a rubber valve is employed as the insertion aperture 46 formed on the tube 44 serving as the blood supply passage 12 so that the needle-detector 40 is easily inserted into the puncture needle 42 from outside. It is possible to employ, as the aperture, any kind of known materials and structures as occasion demands. As to the needle-detector 40, it is generally formed with metal such as stainless steel or with synthetic resin of good biocompatibility (a characteristic not showing adverse effect on blood), for

example, polytetrafluoroethylene, silicone rubber or the like. In consideration of blood vessel damage, it is preferable to make the needle-detector 40 from synthetic resin. It should be understood that, in addition to the above embodiment, various changes, modifications and improvements can be applied based on the knowledge of a person skilled in the art as long as it does not depart from the subject matter of the present invention.

Claims

1. A blood clarification apparatus wherein (1) blood taken out from a blood vessel by an puncture needle is introduced to a blood clarification device via a blood supply passage and is clarified by dialyzing and/or filtering action, and water contained in the blood is removed; and (2) blood pressure inside the blood vessel is continuously measured by a means for measuring blood pressure, and water- removing-rate and/or supplementary-fluid-supplying-rate into a body is controlled based on the measured blood pressure
   characterized in that
   the means for measuring blood pressure comprises
   a needle-detector, which is much thinner than the puncture needle and capable of being smoothly inserted into a blood vessel from outside through an inner aperture of the puncture needle,
   an insertion aperture, for allowing fluid-tight insertion of the needle-detector, positioned on a wall of the blood supply passage in the vicinity of the puncture needle, and
   a pressure transducer for detecting the blood pressure inside the blood vessel transmitted to the pressure transducer via the needle-detector.

FIG. 1

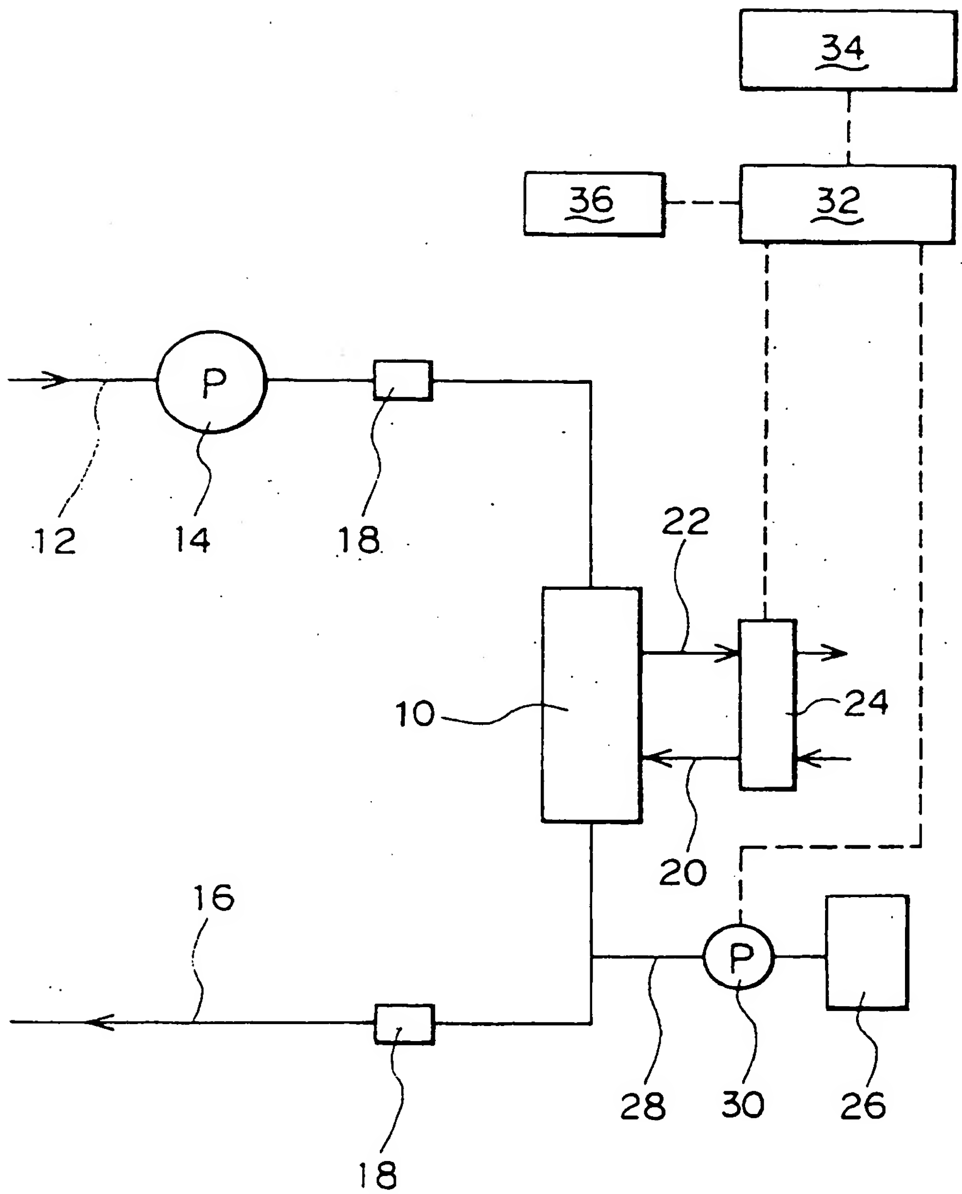


FIG. 2

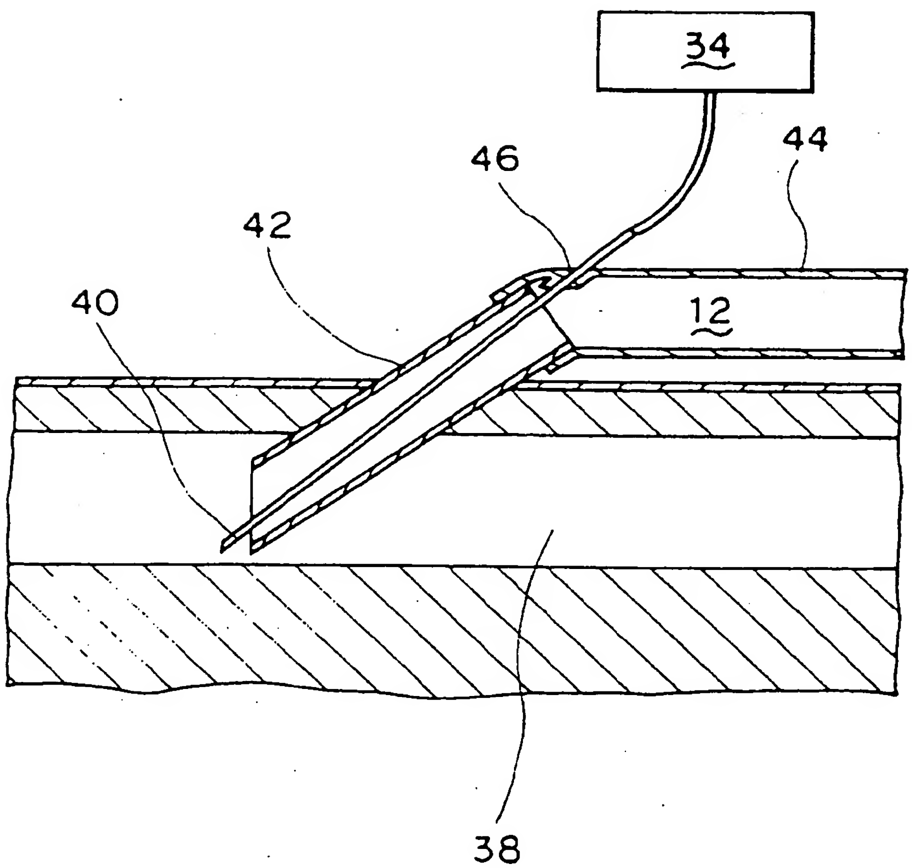


FIG. 3

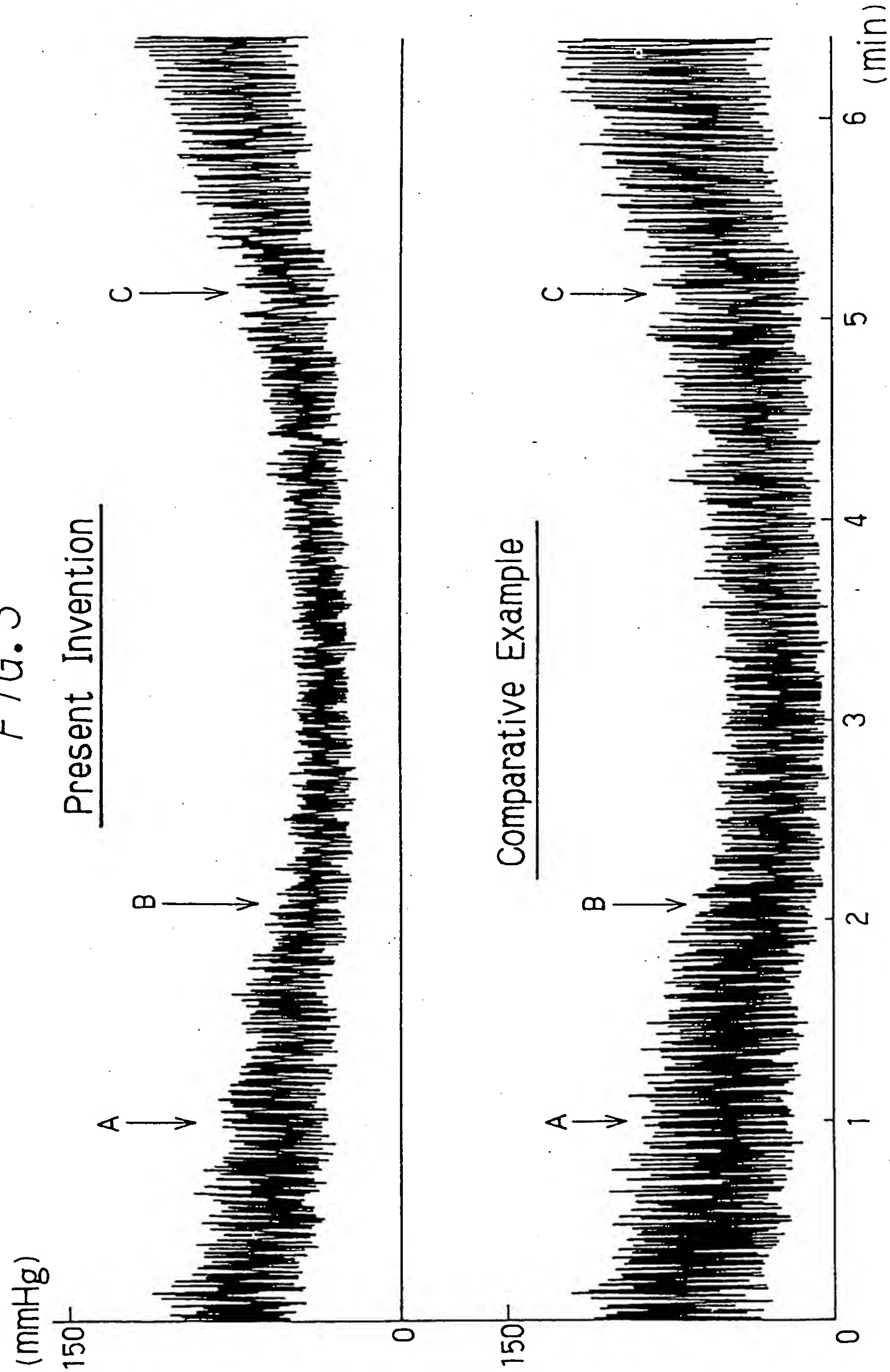
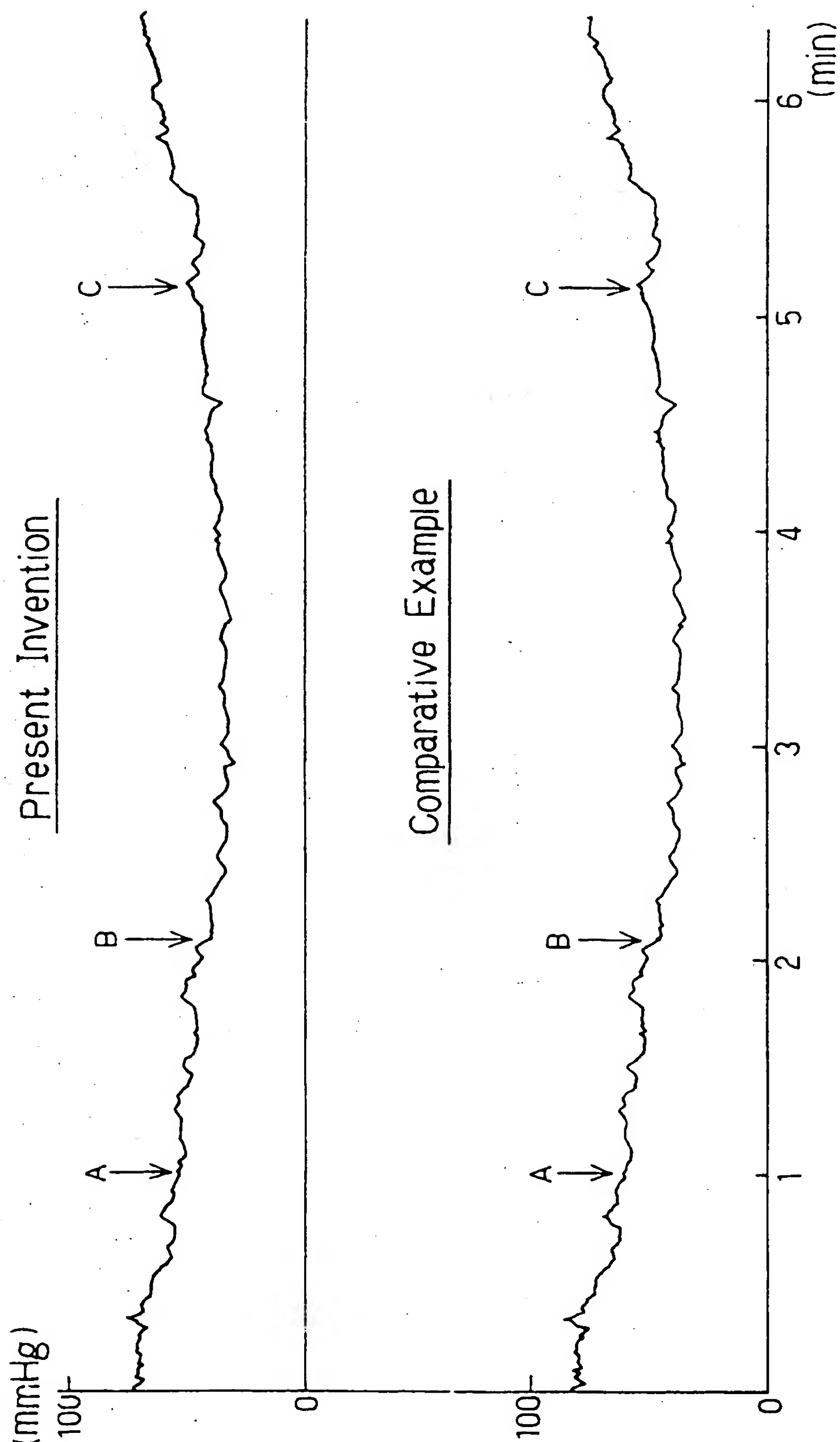

Present Invention
Comparative Example
A
B
C
(mmHg)
150
0
150
0
1
2
3
4
5
6
(min)

FIG. 4


Present Invention
Comparative Example
A
B
C
(mmHg)
100
0
1
2
3
4
5
6
(min)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 92 10 1690

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	FR-A-2 179 980 (A/S NYCOTRON) * claims; figures *	1	A61M1/36 A61M5/48 A61B5/0215
A	US-A-4 928 693 (GOODIN ET AL.) * abstract; figures 1,4 *	1	
A	PATENT ABSTRACTS OF JAPAN vol. 13, no. 95 (C-573)6 March 1989 & JP-A-63 275 322 (KAZUO TAKAYAMA) 14 November 1988 * abstract *	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61M
A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	23 MARCH 1992	ZEINSTRA H.

CATEGORY OF CITED DOCUMENTS

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